DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration Rockville MD 20857

Public Health Service

OCT 19 2004

Re: Factive

Docket Nos. 03E-0448, 03E-0449, and 03E-0411

The Honorable Jon Dudas Acting Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office Box Pat. Ext. P.O. Box 1450 Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 5,776,944; 5,962,468; and 5,633,262 filed by LG Life Sciences, Ltd under 35 U.S.C. § 156. The patents claims Factive (gemifloxacin mesylate), NDA 21-158.

In the March 15, 2004, issue of the Federal Register (69 Fed. Reg. 12160), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before September 13, 2004, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours, Jane a. ayelead

Associate Director for Policy

Center for Drug Evaluation and Research

cc:

Charles E. Van Horn

Finnegan, Henderson, Farabow, Garrett & Dunner

1300 Eye Street, NW

Washington, DC 20005-3315